510k Premarket Notification ANCHORAGE® Bone Plate System MEMOMETAL TECHNOLOGIES	

FEB - 6 2009

SECTION 5: 510(K) SUMMARY

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

As required by section 807.92(c)

Submitter	MEMOMETAL TECHNOLOGIES Campus de Ker Lann - Rue Blaise Pascal 35170 BRUZ – France Phone : + 33 (0)2 99 05 59 69 Fax :+ 33 (0)2 99 05 95 62
Contacts	Gilles AUDIC Quality Manager Bernard PRANDI General Manager e-mail: gilles.audic@memometal.com bernard.prandi@memometal.com
Preparation date	11/17/2008
Trade Name	ANCHORAGE® Bone Plate System
Common Name	Bone Osteosynthesis Bone Plates System
Classification Name	Plate, Fixation, Bone
Legally marketed predicate devices	K061808 DARCO locking bone plate system
Description	MEMOMETAL ANCHORAGE® Bone Plate Systems are single use bone fixation appliances intended to be permanently implanted. They are designed with different shape plates made of biocompatible titanium. The Bone Plate Systems use either 3mm or 3,5mm screws. The drill holes of the plates are aligned to assure the screws do not touch. The plates vary essentially through different curvatures, lengths, number of plate holes and shape.

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Intended Use & Indication for use	The MEMOMETAL ANCHORAGE® Bone Plate Systems are indicated for stabilization and fixation of fresh fractures, revision procedures, joint fusion, and reconstruction of small bones of the hand, feet, wrist and ankles, fingers and toes. The system may be used in both adults and pediatric patients.
Performance data	No clinical or non clinical tests were used in the claim of substantial equivalence.
Substantial equivalence	The MEMOMETAL ANCHORAGE® Bone Plate Systems are substantially equivalent to their predicate devices DARCO locking bone plate system in terms of intended use and indications for use, material, design (thickness, length, number of holes) and function. Any minor differences between these two devices do not raise new questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 6 2009

Memometal Technologies
% Mr. Gilles Audic
Quality Manager/Director
Campus de Ker Lann – Rue Blaise Pascal
35170 BRUZ - France

Re: K083447
Trade/Device Name: ANCHORAGE® Bone Plate System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS
Dated: January 20, 2009
Received: January 23, 2009

Dear Mr. Audic:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

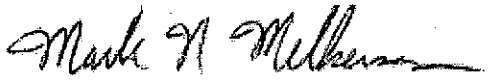
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K083447

Device Name: MEMOMETAL ANCHORAGE® Bone Plate System

Indications for Use:

- The ANCHORAGE® Bone Plate System is indicated for stabilization and fixation of fresh fractures, revision procedures, joint fusion, and reconstruction of small bones of the hand, feet, wrist and ankles, fingers and toes. The system may be used in both adults and pediatric patients.

Prescription Use ✓ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K083447